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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,024	07/25/2003	Michael P. Wallace	03-248 (US01)	3679

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VISTA IP LAW GROUP LLP
12930 Saratoga Avenue
Suite D-2
Saratoga, CA 95070

EXAMINER

JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/627,024	Applicant(s) WALLACE, MICHAEL P.	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-58 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>100703121304</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

On page 1, line 24 the words (not needed) are unclear.

On page 3, line 20 a word is missing.

On page 4, line 22 it is not clear how the implants are positioned as they are not disclosed as part of either member.

On page 7, line 2, the word in should be "is".

On page 10, line 21, it appears a word is missing. On page 12, line 17, there are extra commas.

Appropriate correction is required.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Applicant has two claims numbered 21.

Misnumbered claims 21-57 been renumbered 22-58.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 10-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is rejected as indefinite as the first implant has not been cited as being associated with either member.

Claim 16 is rejected as indefinite as not positive step is cited that would yield a second implant being "contained" by a first implant.

Claims 25 and 40 are indefinite as the first implant has not been positively cited in the base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24, 27, 29, 36-40, 44, 49, 50, 53 and 56-58 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,036,072 to Anidjar et al. Anidjar et al. disclose a means and method for implanting a vascular prosthesis wherein a guidewire (Fig. 3, # 31) is used to guide an introducing tube and introducing means to the treatment site. The introducing means (Fig. 3, # 33) is interpreted as the second member and is inside the introducing tube (Fig. 3, #

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39), the first member. Both have proximal and distal portions and the distal portions are slid over the guidewire (Col. 7, lines 40-44). The introducing means is withdrawn (Col. 7, lines 47-48) and a catheter with the implant is pushed into the introducing tube (Col. 8, lines 8-15). With the second member between the first member and the guidewire, it is inherent it would reduce radial movement. The implant may be a stent (abstract) that inherently acts as a containment implant.

Regarding claims 36-38, 44 and 56-58, the claims rely on intended use rather than structure to define an apparatus.

The last paragraphs of claims 24 and 39 are related to the position of movable structural components during use and are therefore not considered in the apparatus claim.

Claims 24-26, 29-39, 44, and 49-58 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,814,062 to Sepetka et al. Sepetka et al. teach an occlusive implant delivery assembly with a catheter (Fig. 4, #4) positioned by a guidewire that is withdrawn after positioning (Col. 8, lines 10-15), and occlusion coils delivered by the lumen of the catheter by a hollow pushrod (Fig. 4, # 26). The pushrod, having a lumen, is interpreted as a catheter or second member. Sepetka et al. teach the size of the device is dependent on the size of the vascular structure (Col. 7, lines 15-27) and specifically discloses use with vessels of from 2-5 millimeters and deep brain vascular sites (Col. 5, line 53).

Claims 10, 13-15, 17, 19-24, 36-39, 41-47, 49, 53 and 56-58 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2003/0204246 to Chu et al. Chu et al. disclose a system for treating aneurysms including a catheter (Fig. 2, # 30), guidewire (Paragraph 0029), and hollow delivery tube (Fig. 2, # 31) with embolic units (Fig. 2, # 10 & 15). The delivery tube is interpreted as a second member catheter. The catheter and

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delivery tubes are interpreted as delivering the embolic units together and delivering them in sequence, yielding a first implant, second implant, etc.

Regarding claims 44-46, the action of the deployed units is not dependent on structure.

In use, the guides may be positioned by a guidewire that is clearly within the second lumen. Chu et al. implies the two members are aligned during deployment as a radiopaque marker may be located on either (Paragraph 0025). It is inherent that all delivery members would be removed after the implant procedure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0204246 to Chu et al. as applied to claims 39 and 46 above and further in view of U.S. Patent 6,036,072 to Anidjar et al. Both are discussed above. It would have been obvious to one skilled in the art to use the coils as taught by Anidjar et al. in the device of Sepetka et al. as the embolic units as coils are well known for this use in the art.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,036,072 to Anidjar et al. as applied to claim 24 above and further in view of U.S. Patent Application Publication US 2003/0204168 to Bosma et al. Anidjar et al. are discussed above, but do not teach deploying a filter. Bosma et al. disclose deployable vascular devices including a filter for capturing particulate matter (Paragraph 0024). It would have been obvious to one

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skilled in the art to use the filter implant as taught by Bosma et al. in the invention of Anidjar et al. as a safety measure against debris that could potentially cause a stroke or embolism.

Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,036,072 to Anidjar et al. in view of U.S. Patent 5,814,062 to Sepetka et al. Both are discussed above, but Anidjar et al. does not disclose removing the guidewire with the second member. Sepetka et al. teach the removal of the guidewire after positioning and prior to implants the implant device. Anidjar et al. clearly uses the second member to facilitate the positioning by collocating the distal ends. It would have been obvious to one skilled in the art to remove the guidewire as taught by Sepetka et al. during the procedure of Anidjar et al. as such removal is well known in the art. Guidewire for positioning are pervasive and are removed if they interfere with further procedures or may be left in place if they do not interfere with further procedures. Whether to leave or remove would be obvious to a skilled artisan.

Allowable Subject Matter

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 11, 16 and 18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Henry M. Johnson, III
Primary Examiner
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